

**SUMMARY OF THE  
REGULATORY COORDINATION COMMITTEE MEETING  
JULY 11, 2002**

The Regulatory Coordination Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Thursday, July 11, 2002, at 8:00 a.m. Eastern Daylight Time (EDT) during the Eighth Annual NELAC Meeting in Tampa, Florida. Chairperson Kevin Coats of the US Army Corps of Engineers led the meeting. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The purpose of the meeting was to address items of importance identified in the meeting agenda.

**WELCOME AND INTRODUCTION**

Mr. Coats introduced himself and then had the Committee members introduce themselves to the audience. Mr. Coats then called the meeting to order. He noted that this Committee has a vacancy for one state representative and one contributor, although it is not clear at this time if this Committee will go forward under the NELAC restructuring as part of the standards development or standards adoption organization. Mr. Coats reviewed the background as to why the Committee was created and the two primary functions it is to fulfill, as stated in the Constitution and Bylaws. The first function is to provide Standing Committees with current information on regulations and laws that impact laboratory testing and accreditation. The Regulatory Coordination Committee is also responsible for the development of model language for state legislation and regulations that reflect the findings and actions of NELAC.

**CURRENT MODEL LEGISLATIVE LANGUAGE**

Mr. Coats reviewed the Model State Legislative language, which is found on the NELAC website and is shown in Attachment C. The purpose was to familiarize attendees with the model, as well as to promote input for specific comments or need for additional model legislation.

**ADDITIONAL MODEL LEGISLATIVE LANGUAGE**

Mr. Coats has received information to indicate that there is model legislation that would be useful to states that are accommodating NELAP, such as Georgia and Kentucky's adoption of Standards without becoming a NELAP AA (i.e. requirement for compliance data from NELAP accredited labs only). It was noted that Nevada is preparing to become a NELAP AA and, with its regulations already in place, and is requiring that laboratories follow NELAC Standards. Although Vermont, is not interested in becoming a NELAP AA, they also require laboratories to follow NELAC Standards. It was suggested that the committee acquire a copy of this legislation from these states.

As a tool to determine the need for additional model legislative language, the Regulatory Coordination Committee has created a two-tiered Accrediting Authority survey, which is shown in Attachment D. The questions found in the first tier are for states currently a NELAP AA, the second tier for those states that do not have a NELAP AA program. Due to the Reduction of Paper Act, no NELAC committee may send out a survey; however, a member may do so. It is yet to be decided

how this survey will be circulated.

In an effort to get comments from the floor on draft survey, it was asked what types of environmental data must be submitted, as shown under 2.a.(4) of the survey. It was recommended that this question be more specific.

Discussion also ensued regarding fees and the pros and cons of being a NELAC member, with no formal resolutions presented.

#### **REGULATORY SURVEY**

This annual regulatory survey is generated to apprise NELAC or NELAC committees of any regulations that would impact either NELAC itself or the laboratory accreditation process. It is found on the University of Massachusetts' website, listed under *Center for Intelligent Information Retrieval*, which contains government regulatory and deregulatory surveys. The process is currently being evaluated for improvement (e.g. improve the referral process) and will be presented to the board before NELAC 8i.

#### **ACTION ITEMS AND CLOSING**

Mr. Coats is working on the possibility of having this Committee generate comments for NELAC on rules being contemplated on state and federal levels. More details will be presented at NELAC 8i.

#### **ADJOURNMENT**

There being no further business to discuss, the meeting was adjourned.

**ACTION ITEMS  
REGULATORY COORDINATION COMMITTEE MEETING  
July 11, 2002**

<b>Item No.</b>	<b>Action</b>	<b>Date to be Completed</b>
1.	Finalize and Distribute NELAC AA Survey.	ASAP
2.	Review, process, and produce Annual Regulatory Survey.	NELAC 8i

**PARTICIPANTS  
REGULATORY COORDINATION COMMITTEE MEETING  
July 11, 2002**

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STATE OF

DEPARTMENT OF

## CHAPTER 100A-1, ADMINISTRATIVE CODE

## CERTIFICATION OF ENVIRONMENTAL TESTING LABORATORIES

100A-1.005 Laboratory Certification Criteria.

(1) A laboratory certified by the Department of \_\_\_\_\_ pursuant to this rule must comply with the consensus standards adopted at the National Environmental Laboratory Accreditation Conference (NELAC). The NELAC Constitution, Bylaws, and Standards, \_\_\_\_<EPA document number and date for current NELAC Standards>\_\_\_\_, is adopted by reference into this rule.

(2) STATE SUPPLEMENTAL CRITERIA: \_\_\_\_\_  
 \_\_\_\_\_<This section should include any state requirements for additional analytes and methods that are not required under any EPA programs that are part of NELAC; these requirements must not modify any NELAC Standards (see NELAC 1.8.2 and 6.2.1(d)).>\_\_\_\_\_

Specific Authority: \_\_\_\_\_

Law Implemented:

History:            New

100D-1.006 Certification Requirements for Primary Accreditation.

(1) An application for certification shall be made in writing to the Department of \_\_\_\_\_ on Form \_\_\_\_\_, accompanied by the application fee listed in Rule 100A-1.017(2). Form \_\_\_\_\_, "Application for Accreditation of Environmental Testing Laboratories under NELAP," \_\_\_\_ (revision date) is also adopted by reference herein. "NELAP" means the National Environmental Laboratory Accreditation Program, the laboratory certification system derived from laboratories, proficiency test sample providers, and accrediting authorities fulfilling the requirements of the NELAC Standards.

(2) Notwithstanding any other errors or omissions, an application is not completed until the laboratory has fulfilled all of the following requirements:

(a) The application reviewed by the Department of \_\_\_\_\_ includes the signed certification of compliance by laboratory management.

(b) Proficiency samples are successfully analyzed, if available, from a NELAP-approved proficiency test sample provider, for the requested analytes in the applicable sample matrix in at least two out of the latest three testing rounds attempted.

(c) A written Quality Manual has been prepared to include those NELAC-required elements relevant to the requested fields of testing (test methods and analytes).

(d) An on-site laboratory inspection has been conducted within the last two years for the test methods and analytes for which the laboratory is seeking certification, and any deficiencies noted have been corrected with a remedial action plan and estimated completion date acceptable to the department.

(e) Certification fees are paid as required in Rule 100A-1.017(3).

(f) The laboratory's Technical Director or Directors for the requested fields of testing were found to be qualified according to Section 4.1.1 of the NELAC Standards, referenced in Rule 100A-1.005(1).

(3) Applications for certification not completed within 2 years from the date received by the Department of \_\_\_\_\_ shall expire, and certification shall be denied.

(4) State Supplemental Certification Requirements: \_\_\_\_\_  
\_\_\_\_\_  
<This section should include any statements about laboratory facilities in noncontiguous premises requiring separate accreditation, plus any mobile laboratory facilities requiring separate accreditation (see NELAC 4.0).>\_\_\_\_\_

(5) State Scope of Accreditation: \_\_\_\_\_  
\_\_\_\_\_  
<This section should include any requirements or restrictions on which Fields of Testing will be offered for NELAP accreditation, plus the Fields of Testing under which laboratory technical directors may be exempt from personnel qualification requirements (see NELAC 1.5.2.3.1 and 4.1.1.2.>\_\_\_\_\_

Specific Authority: \_\_\_\_\_

Law Implemented: \_\_\_\_\_

History: New \_\_\_\_\_

#### 100A-1.007 Certification Requirements for Secondary Accreditation.

(1) The Department of \_\_\_\_\_ shall certify an out-of-state laboratory to perform environmental sample analyses provided that the laboratory complies with all the requirements in this rule.

(2) An out-of-state laboratory shall be eligible for reciprocal certification to perform environmental sample analyses provided:

(a) The laboratory is certified by a state recognized as a NELAP Accrediting Authority for those fields of testing in which the laboratory is requesting certification pursuant to this rule.

(b) The laboratory submits to the Department of \_\_\_\_\_ an application on Form \_\_\_\_\_, which is adopted herein by reference, with a current copy of the laboratory's certification and a listing of the categories, analytes, and test methods certified.

(3) The Department of \_\_\_\_\_ shall grant certification for those fields of testing after the invoiced certification fees are paid.

Specific Authority: \_\_\_\_\_

Law Implemented: \_\_\_\_\_

History: New \_\_\_\_\_

#### 100A-1.008 Proficiency Testing Requirements.

(1) Laboratories shall bear the cost of any subscription to a proficiency testing program required by the Department of \_\_\_\_\_ for certification purposes. The Department of \_\_\_\_\_ shall not be charged a fee for the analysis of any performance evaluation samples.

(2) After the laboratory has submitted its application form or has become certified by the Department of \_\_\_\_\_, the laboratory must authorize the approved provider, prior to the testing round closing date of subsequent attempts, to submit the proficiency testing results to the Department of \_\_\_\_\_ concurrently with the submittal of these results to the laboratory. Otherwise, the Department of \_\_\_\_\_ shall refuse to consider the proficiency test results from that round for fulfilling the requirements of this rule. A laboratory eligible for reciprocal certification pursuant to Section 100A-1.007 of this rule will have fulfilled these requirements for another NELAP-recognized accrediting authority and is thus exempt from the requirements of this subsection.

(3) Proficiency test sample results shall be considered satisfactory when they are within the acceptance limits established by the approved proficiency test sample provider, according to one of the

scoring options listed in Chapter 2, Appendix C of the NELAC Standards, which is referenced in Rule 100A-1.005(1).

(4) State Supplemental PT Requirements: \_\_\_\_\_  
\_\_\_\_\_  
<This section should include any statements that require laboratories to do PT samples according to a predefined calendar schedule (see NELAC 2.7.6).> \_\_\_\_\_

(5) State Supplemental PT Criteria: \_\_\_\_\_  
\_\_\_\_\_  
<This section should include any statements about laboratory accreditation status based on passing or failing PT samples (see NELAC 2.2.4 and 4.1.4(e)).> \_\_\_\_\_

Specific Authority: \_\_\_\_\_  
Law Implemented: \_\_\_\_\_  
History: \_\_\_\_\_ New \_\_\_\_\_

#### 100A-1.010 On-Site Laboratory Assessments.

(1) The laboratory shall ensure that its documented Quality System, analytical methods, quality control data, proficiency test data, laboratory standard operating procedures, and other records needed to verify compliance with this rule are available for review during the on-site laboratory inspection. The laboratory shall allow the Department's authorized personnel to examine records; observe the laboratory's procedures, facilities, and equipment; and interview staff as necessary to determine such compliance.

(2) The laboratory shall submit to the Department of \_\_\_\_\_ on Form \_\_\_\_\_ a Plan of Correction for each deficiency noted during the on-site evaluation. Form \_\_\_\_\_, "Statement of Deficiencies and Plan of Correction," \_\_ (revision date) \_\_ is herein incorporated by reference.

(3) State Supplemental Requirements: \_\_\_\_\_  
\_\_\_\_\_  
<This section should include any statements on requiring on-site laboratory assessments if any change in ownership or location occurs, frequencies and authorizations for performing on-site assessments, plus any allowances and criteria for adding accreditation without an on-site assessment (see NELAC 4.1.8 and 4.6.2).> \_\_\_\_\_

Specific Authority: \_\_\_\_\_  
Law Implemented: \_\_\_\_\_  
History: \_\_\_\_\_ New \_\_\_\_\_

#### 100A-1.011 Renewal of Annual Certification.

(1) The Department of \_\_\_\_\_ will renew a laboratory's certification after return of the renewal application on Form \_\_\_\_\_ and receipt of the renewal certification fee, provided the laboratory is maintaining compliance with this rule. The Renewal Application, Form \_\_\_\_\_, \_\_ (revision date) \_\_, and Environmental Testing Laboratory Renewal Invoice, Form \_\_\_\_\_, \_\_ (revision date) \_\_, are both herein adopted by reference.

(2) A laboratory's certification shall expire on \_\_ <dates> \_\_\_\_\_, unless its certification has been renewed.

(3) Failure to receive a renewal invoice does not exempt a laboratory from paying the renewal certification fee.

(4) A laboratory whose certification has expired may reapply for certification in accordance with Rule 100A-1.006(1).

Specific Authority: \_\_\_\_\_  
Law Implemented: \_\_\_\_\_  
History: \_\_\_\_\_ New \_\_\_\_\_

#### 100A-1.012 Display of Certificate.

A current Certificate shall be displayed at all times in a prominent place in each certified laboratory where it may be viewed by the public. Form \_\_\_\_\_, \_\_ (revision date) \_\_, "NELAP Testing Laboratory Certificate," is adopted by reference herein.

Specific Authority: \_\_\_\_\_  
Law Implemented: \_\_\_\_\_  
History: \_\_\_\_\_ New \_\_\_\_\_

#### 100A-1.013 Contractual Agreements, Records, and Reports.

##### SPECIFIC STATE REPORTING REQUIREMENTS: \_\_\_\_\_

Specific Authority: \_\_\_\_\_  
Law Implemented: \_\_\_\_\_  
History: \_\_\_\_\_ New \_\_\_\_\_

#### 100A-1.014 Denial or Revocation of Certification.

(1) The Department of \_\_\_\_\_ is authorized to deny, suspend, limit, or revoke the certification of any laboratory that does not comply with the requirements in the NELAC Standards, referenced in Rule 100A-1.005(1), and this rule.

(2) In determining the denial, revocation, suspension or limitation, the Department of \_\_\_\_\_ will consider such factors as the gravity of the offense, the danger to the public of the offense, the intent of the violation, the extent of the violation, and the proposed correction of the problem.

(3) The Department of \_\_\_\_\_ shall take agency action in accordance with \_\_\_\_ (state regulations) \_\_\_\_ and shall afford a person whose substantial interests are affected an opportunity for an administrative hearing in accordance with \_\_\_\_ (state regulations) \_\_\_\_.

(4) The Department of \_\_\_\_\_ is authorized to issue an emergency order immediately suspending the certification of a laboratory when it determines that any condition in the certified laboratory presents a clear and present danger to public health and safety.

Specific Authority: \_\_\_\_\_  
Law Implemented: \_\_\_\_\_  
History: \_\_\_\_\_ New \_\_\_\_\_

#### 100A-1.017 Fees.

(1) \_\_\_\_ (State regulations) \_\_\_\_ authorizes the Department of \_\_\_\_\_ to charge and collect fees for the evaluation and certification of laboratories pursuant to this rule.

(2) A nonrefundable application fee of \_\_\_\_\_ shall accompany each application. Such fee shall be assessed each subsequent application for additional analytes. The Department of \_\_\_\_\_ shall not retain this fee in circumstances where the application is not processed.

(3) In addition to the application processing fee, each laboratory shall pay to the Department of \_\_\_\_\_ the following fees for the initial certification and \_\_\_\_ (time period) \_\_\_\_ renewal for each category of certification as follows:

\_\_\_\_\_  
\_\_\_\_\_  
(4) The Department of \_\_\_\_\_ shall assess the expenses it incurs as a result of on-site inspection to the out-of-state laboratories, in addition to the application and certification fees in Subsections (2) and (3) of this section.

Specific Authority: \_\_\_\_\_



Law Implemented: \_\_\_\_\_  
History: \_\_\_\_\_ New \_\_\_\_\_

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**DRAFT NELAP ACCREDITING AUTHORITY SURVEY**

Goal – promote increase in number of State NELAC Accrediting Authorities through lessons learned, understanding impediments, and development of additional model legislative language

Mechanism – survey individual states regarding current NELAP AA status (planned as collaborative effort of the Regulatory Coordination and Membership & Outreach Committees)

Limitations – (1) survey cannot be conducted directly by a NELAC Committee (Paperwork Reduction Act); and (2) establishing appropriate distribution of survey for best response

**DETAILED SURVEY:**

**1. State is Currently a NELAP AA**

- a. What do you require for secondary accreditation?
- b. Do you currently also maintain non-NELAP environmental lab accreditation program(s)? Which ones?
- c. Provide scope-of-accreditation as a primary NELAP AA (can provide by reference).
- d. Provide reference and POC for current NELAP legislation.
- e. Provide plans for rulemaking to accommodate subsequent versions of NELAC standards.
- f. Provide source for any related rules that require that environmental compliance data be submitted from NELAP accredited labs only.
- g. Provide lessons learned in becoming NELAP AA.
- h. Do you have need for additional model legislation from NELAC or have comments on the posted model (see website for existing model)?

**2. Currently No State NELAP AA Program**

- a. What is your current status regarding establishing a NELAP AA program? (check items (1)-(4) as appropriate)
  - (1) currently pursuing
  - (2) no plans to pursue
  - (3) have existing non-NELAP environmental lab accreditation program(s) for SDWA, CWA, RCRA, UST, Air, Rad., or other? (circle appropriate item(s))
  - (4) have rule that requires that environmental data be submitted from NELAP accredited labs
- b. List impediments to establishing a NELAP AA program.
- c. Do you have need of model legislation from NELAC or have comments on the posted model (see website for existing model)?